ONE HUNDRED EIGHTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

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July 9, 2004

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

As Chairman Davis and I indicated in our letter dated June 17, 2004, over the past two years the Subcommittee on Criminal Justice, Drug Policy, and Human Resources and the office of Chairman Chris Smith have been in correspondence with the NIH regarding the current status of medical therapies and clinical research using adult and embryonic stem cells.

How the Department has allowed this matter to drag on for nearly two years defies excuse or explanation.

On October 8, 2002, Chairman Smith and I sent a letter to Dr. Elias Zerhouni, Director of the National Institutes of Health (NIH), requesting "a detailed report" providing comprehensive information about the medical applications of adult and embryonic stem cells as well as stem cells from cloned embryos and aborted fetuses.

After almost a year had passed, Subcommittee records indicate that on August 4, 2003, Subcommittee staff inquired into the status of the requested report and were told that the letter had been in the office of the Assistant Secretary for Legislation (ASL) "for some months" and would be out "in a few weeks."

On October 14, 2003, Subcommittee staff again inquired into the status of the report and were assured that although "...the letter is in final draft and is going through the clearance process now."

The written inquiries on the status of this report are recorded below. There were also numerous telephone conversations that are unrecorded here. The dates of correspondence from the Subcommittee to HHS regarding our October 8, 2002, letter are as follows:

August 4, 2003
October 14, 2003
October 27, 2003
November 19, 2003
February 10, 2004
March 25, 2004
April 20, 2004
June 17, 2004

After repeated inquiries about the status of the report by email, I sent a formal, written letter to you, Mr. Secretary, on April 20, 2004.

Remarkably, there was no answer to the April 20 letter.

After waiting several weeks for acknowledgement, on June 17, 2004, Chairman Tom Davis of the House Government Reform Committee and I sent another letter communicating our concern about a number of outstanding correspondence and document requests.

On June 18, 2004, the Subcommittee received a letter signed by Dr. James Battey, Director of the National Institutes on Deafness and Other Communication Disorders (NIDCD) and Director of the Stem Cell Task Force, responding to our request for information regarding stem cell therapies.

However, the letter we received did not respond to the plain meaning of our request on October 8, 2002. Instead of a thorough response, it represented only a sampling of the information we requested. Through subsequent phone and email conversations within hours of receiving the response, Subcommittee staff communicated disappointment regarding the quality and depth of the letter we received and asked that the response be revised and completed by June 30, 2004.

In lieu of sending a revised document, at the close of the day on June 30, an HHS Deputy Assistant Secretary requested a meeting with members of the Subcommittee staff to "discuss the response on adult stem cells and how [NIH] may be able to better respond to your inquiries here."

At this meeting on July 2, Subcommittee staff communicated our frustration about the delay in receiving a response from the Department as well as our disappointment regarding the quality of the letter. In order to assist the Department in responding to the

Subcommittee's inquiry, I have included a summary of the meeting that took place, along with an outline of our agreement about the nature of a forthcoming, revised report in response to our October 8, 2002 written request.

The original letter, dated October 8, 2002 requested (italics added):

- "a *comprehensive* listing of *all* medical therapies" which utilize various types of stem cells,

- "a listing of *all* ongoing clinical trials or experiments involving human subjects using these same categories of stem cells,

- "the findings of *any* studies that utilized stem cells or tissues from embryos or fetuses to treat human patients from Parkinson's disease and juvenile diabetes," and

- "a *listing of alternatives* to stem cells from embryos and fetuses that have shown promise in human subjects for treating juvenile diabetes, Alzheimer's, and Parkinson's disease."

In response to our letter, the NIH stated that there are no treatments or ongoing clinical trials utilizing embryonic stem cells or stem cells from cloned embryos or aborted fetuses. The NIH letter also reported the adverse effects resulting from the two known clinical trials using fetal tissue transplantation to treat Parkinson's disease.

However, instead of a comprehensive listing of all medical therapies and a listing of all ongoing clinical trials in which human patients were being treated with adult stem cell therapies, NIH included a sampling of the work ongoing at some NIH Institutes and a listing of NIH-funded clinical trials.

That is not what was requested.

The Subcommittee identified several obvious omissions in Dr. Battey's letter.

(1) From the NIH website www.clinicaltrials.gov, in the NIH National Library of Medicine *Medline* database, and in the popular press, Subcommittee staff identified extramurally funded clinical trials and clinical research involving human patients which were not included the NIH letter, including some that began as early as 1999 and should have been available to Dr. Battey prior to his submission of the letter to the ASL office in November 2002. A selection of extramurally funded clinical trials not included in the NIH letter are listed below:

• Sponsor: Baylor College of Medicine
Stem Cell Transplant to Treat Patients with Systemic Sclerosis
Phase I H7157
Study start date: June 1999
Date last reviewed: March 2004

•Sponsor: Texas Heart Institute, Houston, Texas
Transendocardial, Autologous Bone Marrow Cell Transplantation for Severe, Chronic Ischemic Heart Failure, announced in media April 16, 2004.
www.genomenewnetwork.org/articles/2004/04/16/stem_cell_trial.php
Circulation. 2003 May 13;107(18):2294-302.

• Sponsor: Caritas St. Elizabeth's Medical Center of Boston
Stem Cell Study for Patients with Heart Disease 00165
Study start date: January 2004
Date last reviewed: April 2004

• Sponsor: Bioheart, Inc.
Autologous Cultured Myoblasts (BioWhittaker) Transplanted via Myocardial Injection
Phase I BMI-US-01-001
Study start date: June 2003
Date last reviewed: December 2003

• Sponsor: Bioheart, Inc.
MYOHEART™ (Myogenesis Heart Efficiency and Regeneration Trial)
Phase I BMI-US-01-002
Study start date: February 2003
Date last reviewed: December 2003

In response, Dr. Battey maintained that the intent of NIH was to provide a comprehensive listing of work funded by NIH, but not by universities or pharmaceutical companies, citing the difficulty of enforcing compliance with a law (PL105-115, signed November, 1997) mandating that privately funded trials also be listed on the www.clincaltrials.gov website.

Nonetheless, Subcommittee staff were also able to identify several intramurally funded clinical trials at www.clinicaltrials.gov, in which human patients are being treated with adult stem cell therapies, which, astonishingly, were not included in the NIH response:

• **NIAMS (National Institute of Arthritis and Musculoskeletal and Skin Diseases)**
Autologous Stem Cell Transplant for Systemic Sclerosis
Phase I N01 AR-9-2239
Study start date: July 2002
Date last reviewed: March 2004

• **NINDS (National Institute of Neurological Disorders and Stroke)**
Investigating Endothelial Precursor Cells 03-N-0269
Study start date: August 1, 2003
Date last reviewed: August 1, 2003

• **NHLBI (National Heart, Lung, and Blood Institute)**
The Effect of Exercise on Stem Cell Mobilization and Heart Function in Patients Undergoing Cardiac Rehabilitation 03-H-0086
Study start date: January 28, 2003
Date last reviewed: December 5, 2003

Stem Cell Mobilization to Treat Chest Pain and Shortness of Breath in Patients with Coronary Artery Disease 02-H-0264
Study start date: August 6, 2002
Date last reviewed: July 17, 2003

• **NIDCR (National Institute of Dental and Craniofacial Research)**
Bone Regeneration Using Stromal Cells 94-D-0188
Study start date: August 3, 1994
Date last reviewed: June 4, 2003

(2) The Subcommittee also identified several reports of clinical research not yet in clinical trials that were also missing from the report. Some of these studies, reported in peer-reviewed journals and in the public media are listed below:

• **Preliminary clinical research using adult skeletal myoblasts to repair injured heart muscle:**

Pagani, et al, 2003. *Autologous skeletal myoblasts transplanted to ischemia-damaged myocardium in humans. Histological analysis of cell survival and differentiation.* J Am Coll Cardiol. Mar 5;41(5):879-88.

Hagege, et al, 2003. *Viability and differentiation of autologous skeletal myoblast grafts in ischaemic cardiomyopathy.* Lancet. Feb 8;361(9356):491-2.

Menasche, et al, 2003. *Autologous skeletal myoblast transplantation for severe postinfarction left ventricular dysfunction.* J Am Coll Cardiol. 2003 Apr 2;41(7):1078-83.

• Autologous bone marrow or blood cells transplanted into injured heart:

Dr. Cindy Grines at Beaumont Hospital, Royal Oak, Michigan:
http://www.cnn.com/2003/HEALTH/conditions/03/06/teen.heart.ap/
http://www.sctline.com/info/english_viewarticle.asp?id=1966

Assmus et, al, 2002. *Transplantation of Progenitor Cells and Regeneration Enhancement in Acute Myocardial Infarction (TOPCARE-AMI).* Circulation. 2002 Dec 10;106(24):3009-17.

Dobert, et al, 2004. *Transplantation of progenitor cells after reperfused acute myocardial infarction: evaluation of perfusion and myocardial viability with FDG-PET and thallium SPECT.* Eur J Nucl Med Mol Imaging. 2004 Apr 3 [Epub ahead of print]

(3) Included in the response from NIH was an enclosure from the National Bone Marrow Donor Program entitled "Diseases Treatable by Stem Cell Transplantation," dated 2002. However, this list contained only blood disorders, autoimmune diseases, and related cancers treatable with hematopoietic stem cells. The letter did not include a more updated, comprehensive listing of additional diseases treated with hematopoietic or other adult stem cell types.

When questioned about these omissions, Dr. Battey conceded that the report was not comprehensive. The wide range of information missing from the NIH response to our October 8, 2002 letter demonstrates the need for NIH to review responses to ensure that Congress receives accurate and thorough information in response to its requests.

Dr. Battey also indicated that he had made a decision when responding to the letter to include only NIH information that would be difficult for Congress to obtain through publicly accessible sources.

However, Subcommittee staff reiterated to HHS staff at the meeting that our request for a comprehensive document remained unchanged and unfulfilled.

In response to Subcommittee documentation of the inadequacy and omissions of the NIH response, Dr. Battey apologized.

Dr. Battey agreed he and his colleagues would assemble a comprehensive report as requested on October 8, 2002. Subcommittee staff agreed to give a time extension to the $27 billion agency.

Dr. Battey and Subcommittee staff agreed that the revised report would:

(1) be comprehensive in scope as originally requested, including both NIH funded research as well as privately funded research in the public domain, including studies abroad,

(2) be in a format that is easily accessible and searchable,

(3) include anecdotal reports of clinical research when these reports appear substantive and likely to lead to future clinical research and/or clinical trials, and

(4) include only minimal analysis necessary for translating the factual components of the report into lay terms.

The Subcommittee staff and the Department also agreed that an iterative response would be provided to Senator Brownback in advance of his July 14, 2004, hearing on adult stem cell research.

Subcommittee staff emphasized that this report will be an invaluable resource as Congress seeks to make policy decisions and educate the public based on accurate and in-depth scientific data rather than the often-misleading information that is readily available from the news media and lobbying groups.

I appreciate your attention to this matter and your assurances that the Department will be more responsive to matters of Congressional oversight. This, as you know, is not a peripheral issue of concern only to a small number of people. I would think, on an issue of this magnitude, that HHS would have wanted to have this report available in response not only to Congress but for the President and others to whom such information might be important.

It is my hope that as members of Congress and their staff continue to face critical and complex science policy issues they will be able to draw on accurate, thorough, timely, and up-to-date information from the Department of Health and Human Services.

Sincerely,

Mark Souder

Mark E. Souder,
Chairman
Subcommittee on Criminal Justice, Drug Policy,
and Human Resources